

PATENT COOPERATION TREATY

From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:  
PETER F. CORLESS  
EDWARDS & ANGELL, LLP  
PO BOX 9169  
BOSTON, MA 02209

PCT

NOTIFICATION OF TRANSMITTAL OF  
INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT

(PCT Rule 71.1)

Date of Mailing  
(day/month/year)

24 MAR 2005

Applicant's or agent's file reference  56792-PCT		IMPORTANT NOTIFICATION	
International application No.	International filing date (day/month/year)		Priority date (day/month/year)
PCT/US03/00531	07 January 2003 (07.01.2003)		07 January 2002 (07.01.2002)
Applicant  JOHN HOPKINS UNIVERSITY			

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/US  Mail Stop PCT, Attn: IPEA/ US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450  Facsimile No. (703) 305-3230	Authorized officer  Alana M. Harris, Ph.D. Telephone No. 571-272-1600
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*Valerie Bell Harris*  
ALANA M. HARRIS, Ph.D.  
PRIMARY EXAMINER

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## PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

## (PCT Article 36 and Rule 70)

Applicant's or agent's file reference 56792-PCT	FOR FURTHER ACTION		See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/US03/00531	International filing date (day/month/year) 07 January 2003 (07.01.2003)	Priority date (day/month/year) 07 January 2002 (07.01.2002)	
International Patent Classification (IPC) or national classification and IPC IPC(7): C12Q 1/68; C12P 21/06; G01N 33/53; C12N 5/20; C07K 16/30 and US Cl.: 435/344.1, 172.2, 70.21, 344, 240.27, 6, 69.1, 7.2, 7.23; 530/300, 350			
Applicant <u>JOHNS HOPKINS UNIVERSITY</u>			
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>7</u> sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of <u>  </u> sheets.</p>			
<p>3. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> <li>I <input checked="" type="checkbox"/> Basis of the report</li> <li>II <input type="checkbox"/> Priority</li> <li>III <input type="checkbox"/> Non-establishment of report with regard to novelty, inventive step and industrial applicability</li> <li>IV <input type="checkbox"/> Lack of unity of invention</li> <li>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</li> <li>VI <input type="checkbox"/> Certain documents cited</li> <li>VII <input type="checkbox"/> Certain defects in the international application</li> <li>VIII <input type="checkbox"/> Certain observations on the international application</li> </ul>			

Date of submission of the demand 25 July 2003 (25.07.2003)	Date of completion of this report 14 March 2005 (14.03.2005)
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPBA/ US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer Alana M. Harris, Ph.D. Telephone No. 571-272-1600

Form PCT/IPEA/409 (cover sheet)(July 1998)

  
 ALANA M. HARRIS, PH.D.

PRIMARY EXAMINER

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## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US03/00531

**I. Basis of the report**

## 1. With regard to the elements of the international application:\*

 the international application as originally filed. the description:pages 1-49 as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_ the claims:pages 50-60 as originally filed  
pages NONE, as amended (together with any statement) under Article 19  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_ the drawings:pages 1-11 as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_ the sequence listing part of the description:pages NONE as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_

## 2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item. These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

 the language of a translation furnished for the purposes of international search (under Rule 23.1(b)). the language of publication of the international application (under Rule 48.3(b)). the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

## 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing

 contained in the international application in printed form. filed together with the international application in computer readable form. furnished subsequently to this Authority in written form. furnished subsequently to this Authority in computer readable form. The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished. The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.4.  The amendments have resulted in the cancellation of: the description, pages NONE the claims, Nos. NONE the drawings, sheets/fig NONE5.  This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.  
PCT/US03/00531

## V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

## 1. STATEMENT

Novelty (N)	Claims <u>64-66 and 70</u>	YES
	Claims <u>1-4, 13, 39, 40, 46-50, 54-56, 62 and 63</u>	NO
Inventive Step (IS)	Claims <u>64-66 and 70</u>	YES
	Claims <u>1-12, 13-53, 57-61, 67-69, 71-80</u>	NO
Industrial Applicability (IA)	Claims <u>1-80</u>	YES
	Claims <u>NONE</u>	NO

## 2. CITATIONS AND EXPLANATIONS

Claims 1-4, 13, 39, 40, 46-50, 54-56, 62 and 63 lack novelty under PCT Article 33(2) as being anticipated by U.S. Patent number 5,650,291 (issued July 22, 1997). The patent teaches a method for detection and diagnosis of cancer comprising detecting a biomarker having a molecular weight of about 60 kD, see column 2, lines 41-45. The biomarker is designated CA 125 and is shown to be correlated to ovarian cancer, see abstract. Monoclonal antibodies immunoreactive with the tumor-associated antigen, CA 125 were disclosed in the patent. Antibodies were able to recognize antigens with molecular weights ranging from 25 to 65 kd, see column 16, lines 46-54. This range spans the protein markers IV-VI. The monoclonal antibodies were useful in locating tumor tissue in patients and serum levels, see column 7, lines 43 and 44; Example 2 and Example 3 beginning at column 10, line 52. The patent also teaches a diagnostic or therapeutic kit comprising monoclonal antibodies immunoreactive with the CA 214 antigen, bridging sentence of columns 2 and 3.

Claims 1-63, 67-69 and 71-80 lack an inventive step under PCT Article 33(3) as being obvious over U.S. Patent number 5,650,291 (issued July 22, 1997). The patent does not teach a method for detection and diagnosis of cancer comprising detecting a plurality of biomarkers by comparing protein profiles using a biochip array, logarithmic transformation, process for generating data on immobilized marker fractions or compositions comprising markers having molecular weights of 9.2 kD, 19.8kD and 79kD. However, if one could detect other molecular weights listed in the patent one with skill would have been able to detect the other weights and comprise the information in a fashion accessible for other scientists.

Claims 64-66 and 70 the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a composition comprising Marker I, II, III and one more biomarkers.

----- NEW CITATIONS -----